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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 1998D–1146]**

# Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concerns

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

**DATES:** Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974, or e-mail comments to *Fumie_Yokota@omb.eop.gov.*

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B–41, Rockville, MD 20857, 301–827–1472.

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**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concerns**

This guidance document discusses a recommended approach for assessing the antimicrobial resistance concerns as part of the overall preapproval safety evaluation of new animal drugs, focusing on the microbiological effects on bacteria of human health concern. In particular, the guidance describes a methodology sponsors of antimicrobial new animal drug applications for food-producing animals may use to complete a qualitative antimicrobial resistance risk assessment. This risk assessment should be submitted to FDA for the purposes of evaluating the safety of the new animal drug to human health. The guidance document outlines a process for integrating relevant information into an overall estimate of risk and discusses possible risk management strategies.

Table 1 of this document represents the estimated burden of meeting the new reporting requests. The burden estimates for these information collection requests are based on information provided by the Office of New Animal Drug Evaluation, Center for Veterinary Medicine. The guidance document describes the type of information that should be collected by the drug sponsor when completing the antimicrobial resistance risk assessment. FDA will use the risk assessment and supporting information to evaluate the safety of original (21 CFR 514.1) or supplemental (21 CFR 514.8) new animal drug applications (NADAs) for antimicrobial drugs intended for use in food-producing animals.

In the **Federal Register** of September 13, 2002 (67 FR 58058), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received in response to that notice.

FDA estimates the burden for this collection of information:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section 514.1(b)(8) and 514 8(a)(2) | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Hazard Identification (initial scoping of issues--relevant bacteria, resistance determinants, food products; preliminary data gathering) | 5 | 1 | 5 | 30 | 150 |
| Release Assessment (literature review; review of research reports; data development; compilation, and presentation) | 5 | 1 | 5 | 1,000 | 5,000 |
| Exposure Assessment (identifying and extracting consumption data; estimating probability of contamination on food product) | 5 | 1 | 5 | 8 | 40 |
| Consequence Assessment (review ranking of human drug importance table) | 5 | 1 | 5 | 4 | 20 |
| Risk Estimation (integration of risk components; development of potential arguments as basis for overall risk estimate) | 5 | 1 | 5 | 12 | 60 |
| Risk Management (discussion of appropriate risk management activities) | 5 | 1 | 5 | 30 | 150 |
| Total Burden | | | | | 5,420 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

[2]FDA estimates that on an annual basis an average of five NADAs (including original applications and major supplements) would be subject to information collection under this guidance. This estimate is based on a review of the number of major NADA approvals that occurred between October 1997 and October 2001. During that 4-year period, an average of five antimicrobial NADAs (including original and major supplements) was approved in food-producing animals per year. This estimate excludes NADAs for antimicrobial drug combinations, generic drug applications (abbreviated new animal drug applications), and certain supplemental NADAs.

Dated: 9-15-03

September 15, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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